

**Client Newsletter**

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**Stark Law to Include Nuclear Medicine Services**

On November 21, 2005, the Centers for Medicare and Medicaid Services (“CMS”) announced that the Stark Law will be amended to preclude physicians from referring patients for nuclear medicine services to an entity with which the physician, or a member of his or her immediate family, has a financial relationship. The prohibition of such referral goes into effect on January 1, 2007.

The Stark Law (42 U.S.C.A., §1395nn) or Physician Self-Referral Law, precludes a provider from referring Medicare-Medicaid beneficiaries for designated health services to entities with which they, or members of their immediate family, have a financial relationship. The designated health services include: clinical laboratory services; physician therapy services; occupational therapy services; radiology services (including MRIs, CAT Scans and ultrasound services); radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; out-patient prescription drugs; and in-patient and out-patient hospitalization services. The Stark Law defines a “financial relationship” as an ownership/investment interest in an entity or a direct or indirect compensation arrangement with an entity. A compensation arrangement includes any arrangement involving any remuneration (direct or indirect, overt or covert, in cash or in kind) between a physician and an entity. The possible penalties under the Stark Law include: (1) denial of payment and an obligation to refund payments made as a result of a tainted referral; (2) civil monetary penalties of up to \$15,000.00 for each referral that a person “knows or should know” violates the Stark Law; (3) civil monetary penalties of up to \$100,000.00 for schemes to circumvent the Stark Law; (4) possible exclusion from the Medicare and Medicaid programs; and/or (5) liability under the False Claims Act.

CMS’ announcement on November 21, 2005, which was contained within the *Federal Register*, states that the designated health services under the Stark Law will be expanded to include nuclear medicine. As a result, physicians will be precluded from referring patients for nuclear medicine services to entities with which they, or members of their immediate family, have a financial relationship. Therefore, a physician who has invested in either nuclear medicine equipment or a facility that

provides nuclear medicine services, is now faced with three options: (1) divest their ownership interest in the nuclear medicine equipment or the facility which provides nuclear medicine; (2) restructure the financial relationship so it complies with an existing Stark Law exception (i.e. in-office ancillary service exception, space and equipment lease exception, personal services arrangement exception, fair market value compensation exception, etc.); or (3) maintain the ownership interest and refer patients for nuclear medicine services to another entity.

In its announcement, CMS stated that it had decided not to grandfather existing financial relationships between physicians and nuclear medicine facilities. Therefore, CMS is encouraging physicians and hospitals to review current nuclear medicine relationships to determine whether changes will need to be made in order to comply with the amended Stark Law.

## **IRS May Expand Tax Exempt Compensation Enforcement Project**

In 2005 the IRS announced the Tax Exempt Compensation Enforcement Project (“Project”) to address the issue of excessive compensation being paid to insiders of charities and private foundations. As part of this Project, the IRS’ Exempt Organizations Compliance Unit (“EOCU”) mailed approximately 1,250 compliance-check letters to exempt organizations. Based upon these compliance-check letters, the EOCU initiated a significant number of field examinations. The IRS is expected to complete these field examinations during Fiscal Year 2006 and issue a report on its initial findings.

On October 26, 2005, the IRS Tax Exempt and Government Entities Division announced its enforcement and guidance plan for Fiscal Year 2006 in a document entitled “FY 2006 Exempt Organizations Implementing Guidelines”. The FY 2006 Exempt Organizations Implementing Guidelines states that the EOCU is now considering a potential compliance project which would involve sending a questionnaire to a significant number of hospitals asking them to provide information on how they determine and pay compensation, as well as how they meet the community benefit standards for purposes of section 501(c)(3). The community benefits standard was established by the IRS in Revenue Ruling 69-545. The community benefit standard provides that in order to qualify for tax-exempt status, the organization must establish the presence of significant factors which demonstrate that their organization’s operations promote the health of a class of person broad enough so that the community as a whole benefits. Factors considered by the IRS to meet this standard include: a community board, an open medical staff, a full-time emergency room (regardless of the ability of patients to pay), and the organization serves a broad cross-section of the community.

If the EOCU expands its Tax Exempt Compensation Enforcement Project to specifically address hospital compensation, hospitals and health care organizations can expect to incur substantial time and expense gathering data in preparing responses to the EOCU’s questionnaire. The announcement of this proposed initiative comes at a time when Congressional Committees, most notably the Senate Finance Committee and the House Ways and Means Committee, are examining the standards for tax exempt status. The proposed IRS initiative indicates that the IRS is prepared to address tax exempt entities, and in particular their executive compensation, whether or not Congress takes action.

## JCAHO 2006 National Patient Safety Goals and Requirements

The Joint Commission on Accreditation of Health Care Organizations (“JCAHO”) has announced a new standard pertaining to “hand-off communications” within a hospital. This new standard was announced as part of JCAHO’s “2006 National Patient Safety Goals and Requirements” (“Patient Safety Goals”). The Patient Safety Goals apply to the following accreditation programs: ambulatory care and office based surgery, assisted living, behavioral health care, critical access hospitals, disease-specific care, home care, hospitals, laboratories, long-term care and Medicare/Medicaid certification-based long-term care, and health care networks. The Patient Safety Goals state that the goal with respect to hand off communications is to improve the effectiveness of communication among caregivers. Therefore, hospitals are required to implement a standardized approach to hand-off communications, including an opportunity to ask and respond to questions.

The JCAHO “2006 National Patient Safety Goals Implementation Expectations” (“Implementation Expectations”) provide that the primary objective of a hand-off is to provide accurate information about a patient’s treatment and services, current condition and any recent or anticipated changes. JCAHO points out that the “information communicated during a hand-off must be accurate in order to meet patient safety goals.” According to JCAHO there are numerous types of patient hand-offs, including but not limited to, nursing shift changes, physicians transferring complete responsibility for a patient, physicians transferring on-call responsibility, temporary responsibility for staff leaving the unit for a short time, anesthesiologist’s report to post-anesthesia recovery room nurse, nursing and physician hand-off from the emergency department to in-patient units, different hospitals, nursing homes and home health care, clinical laboratory and radiology results sent to physician offices.

The Implementation Expectations state that the following are attributes of effective hand-off communications:

- Hand-offs are interactive communications allowing the opportunity for questions between the giver and receiver of patient information.
- Hand-offs include up-to-date information regarding the patient’s care, treatment and services, condition and any recent or anticipated changes.
- Interruptions during hand-offs are limited to minimize the possibility that information would fail to be conveyed or would be forgotten.
- Hand-offs require a process for verification of the received information, including repeat-back or read-back, as appropriate.
- The receiver of the hand-off information had an opportunity to review relevant patient historical data, which may include previous care, treatment and services.

The other two new requirements for hospitals which are contained in the 2006 National Patient Safety Goals are as follows: (1) label all medications, medication containers (for example syringes, medicine caps, basins) or other solutions on and off the sterile field; and (2) implement a fall reduction program and evaluate the effectiveness of the program.

The effective date for the Patient Safety Goals is **January 1, 2006**.

## **HHS Proposes New Regulations Regarding E-Prescribing and Electronic Health Records**

The U.S. Department of Health and Human Services (“HHS”) recently issued two proposed regulations pertaining to e-prescribing and electronic health records. These regulatory proposals, one from the Centers for Medicare and Medicaid Services (“CMS”), and the other from the Office of Inspector General (“OIG”), are designed to accelerate the use and adoption of electronic prescribing (“e-prescribing”) and electronic health records. The CMS proposed rule would create exceptions to the Stark Law by allowing hospitals, group practices and other health care organizations to provide physicians with the hardware, software and technical training necessary to support e-prescribing and electronic health records. The OIG proposed rule would provide hospitals and other entities a safe harbor from the Federal Anti-Kickback Statute for donating health records, software and training services to physicians.

The Medicare Modernization Act of 2003 (“MMA”), which created Medicare Part D, the prescription drug benefit, requires protections for e-prescribing technology. The MMA requires drug plans participating in the new prescription drug benefit to support e-prescribing, but it will be voluntary for physicians and pharmacies. Although e-prescribing is voluntary for physicians under MMA, there has been a continued effort by President Bush to encourage physicians to adopt e-prescribing and electronic health records. However, under both the Stark Law and the Anti-Kickback Statute, hospitals and health care organizations are generally prohibited from providing physicians with hardware, software, and technical training necessary for e-prescribing and electronic health records. The Stark Law (42 U.S.C.A. §1395nn), or Physician Self-Referral Law, precludes a provider from referring Medicare/Medicaid beneficiaries for designated health services to entities with which they, or members of their immediate family, have a financial relationship. The Anti-Kickback Statute provides for criminal penalties for offering or accepting remuneration of any kind in exchange for a health care referral.

When MMA was first announced there was great concern in the health care industry regarding how to encourage providers to adopt e-prescribing and electronic health records. Although hospitals, group practices and other health care organizations were willing to provide this technology and support to providers, they were concerned about violating the Stark Law or the Anti-Kickback Statute. As a result, MMA required HHS to adopt regulations which would allow hospitals, group practices and other health care organizations to provide this support to providers without violating the Stark Law or Anti-Kickback Statute.

In regard to e-prescribing, the criteria for the Stark Law exception (CMS proposed rule) and the Anti-Kickback safe harbor (OIG proposed rule) are essentially the same under both proposed rules. The only noticeable difference is that the OIG proposed rule seeks to create a safe harbor for “Donors” to give “Recipients” the technology necessary to transact e-prescribing. Permissible Donors are hospitals (to members of their medical staff), Prescription Drug Plans (PDPs) or Medicare Advantage (MA) plans (to prescribers and pharmacies) and medical groups (to their members). The CMS proposed rule focuses on physicians and their staff as the “Recipients”.

The following is a list of the specific elements of the Anti-Kickback safe harbor and Stark Law exception under the prepared rules:

- The items and services must be used to access an e-prescription drug program that meets Medicare standards;

- The donor may not restrict the use or compatibility of the items or services with other systems;
- The donor may not restrict the recipient’s ability to use the items or services for any patient;
- The recipient may not make the receipt of the items or services a condition of doing business with the donor;
- Neither the eligibility nor the amount of the items or services may be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- The arrangement must be set forth in a written agreement that:
  - is signed by the parties;
  - specifies the items or services being provided and the value of those items and services;
  - covers all of the e-prescribing items and services to be furnished by the donor (or affiliated parties) to the recipient; and
  - contains a certification by the recipient that the items or services are not “technically or functionally equivalent” to items and services the recipient already has.
- The donor must not have actual knowledge of or otherwise act in reckless disregard or ignorance of the fact that the recipient already had technically or functionally equivalent items to those donated (i.e., the hospital-donor cannot give the physician-recipient a new computer if he already has a computer).

In regard to electronic health records, CMS and OIG took different approaches. The OIG decided to solicit comments before formalizing any language into a rule. The OIG is seeking public comment with respect to the following issues: whether the e-prescribing software should allow physicians to order supplies or laboratory tests; whether and how to address recipients who give away their technology in order to get the free replacement technology. The CMS proposed rule regarding electronic health records proposes similar elements to those offered in the e-prescribing exception. The items and services donated must be “necessary” and “used solely” to receive, transmit and maintain electronic health records. The additional requirements to the electronic health record proposed rule are as follows: (1) the electronic health record technology must contain e-prescribing capability that complies with Medicare Part D standards; and (2) the arrangement must not violate the Anti-Kickback Statute.

Once the OIG and CMS have had an opportunity to review the public comments on the proposed rules, both offices will issue final regulations. The Rogers Law Firm will continue to monitor this subject and will provide updates accordingly.

## JCAHO Announces Additional Reviewable Sentinel Events

The Joint Commission on Accreditation of Health Care Organizations (“JCAHO”) recently announced that its list of “Reviewable Sentinel Events” has been expanded to include the following: (1) severe neonatal hyperbilirubinemia (bilirubin more than 30 milligrams/deciliter); and (2) radiation overdoses involving prolonged fluoroscopy with cumulative dose more than 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or more than 25 percent above the planned radiotherapy dose. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, which triggers the need for immediate investigation and response.

Although it is not required, JCAHO encourages hospitals to report Reviewable Sentinel Events to JCAHO. Reviewable Sentinel Events include any occurrence that meets any of the following criteria:

- The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition; or
- The event is one of the following:
  - Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge
  - Unanticipated death of a full term infant
  - Abduction of any individual receiving care, treatment or services
  - Discharge of an infant to the wrong family
  - Rape
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
  - Surgery on the wrong individual or wrong body part
  - Unintended retention of a foreign object in an individual after surgery or other procedure
  - Severe neonatal hyperbilirubinemia (bilirubin more than 30 milligrams/deciliter)
  - Radiation overdose involving prolonged fluoroscopy with cumulative dose more than 1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or more than 25 percent above the planned radiotherapy dose

A hospital which has a Reviewable Sentinel Event must prepare a thorough and credible Root Cause Analysis (a process for identifying the basic or causal factors that underlie variation in performance) and an

Action Plan (the product of the Root Cause Analysis which identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future) within 45 calendar days of the event or becoming aware of the event. According to JCAHO, regardless of whether a sentinel event is “reviewable” or not, a hospital should conduct a Root Cause Analysis and Action Plan for each such event.

It should be emphasized that absent a judicial finding that JCAHO is a medical peer review committee, as that term is defined by the Massachusetts Medical Peer Review Statute, it is unlikely that any sentinel event documents or information disclosed to JCAHO will be protected from disclosure in a civil litigation context.

## **OIG Issues Draft Compliance Program Guidance for Recipients of PHS Research Awards**

On Monday, November 28, 2005, the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services, issued a draft “*Compliance Program Guidance for Recipients for PHS Research Awards*” (“*Guidance*”). The *Guidance* is intended for recipients of extramural research awards from the National Institutes of Health (“NIH”) and other agencies of the U.S. Public Health Service (“PHS”). The purpose of the *Guidance* is to encourage the use of internal controls to effectively monitor adherence to applicable statutes, regulations and program requirements. As part of this *Guidance*, the OIG identifies the following examples of the risk areas for recipients of PHS research awards:

(a) Time and Effort Reporting

The *Guidance* states that because the compensation for the personal services of researchers, including direct salaries and fringe benefits, is typically a major part of the project, it is critical that the portion of the researcher’s compensation for particular research projects be accurately reported. The OIG noted that many researchers typically have multiple responsibilities, including teaching, research and clinical work. The separation between these areas of activity can sometimes be hard to discern, which heightens the need to have effective time-keeping systems. The *Guidance* states that the failure to maintain accurate time and effort reporting may result in overcharges to funding sources and, in certain circumstances, could subject an institution to civil or criminal fraud investigations.

(b) Properly Allocating Charges to Work Projects

The *Guidance* notes that research institutions commonly receive multiple awards for a single research area. Therefore, it is essential that accounting systems properly separate the amount of funding from each funding source. The *Guidance* suggests that “failure to account accurately for charges to various award projects can result in significant disallowances or, in certain circumstances, could subject an institution to criminal or civil fraud investigations.”

(c) Reporting Financial Support from other Sources

The reporting of financial support from other sources is critical for the awarding agency to understand the commitment of resources by the grantee to a particular project or award. In some instances, the failure to identify other support for a research project could cause PHS to provide duplicate funding to the project. The *Guidance* notes that for PHS awards, the reporting of other financial support is a required element of award applications. The failure to provide this information could, in certain circumstances, subject an institution to a criminal or civil fraud investigation.

The *Guidance* sets forth eight elements of an effective compliance program: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication; (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; (7) responding promptly to detected problems and undertaking corrective action; and (8) defining roles and responsibilities and assigning oversight responsibility.

The OIG notes that many institutions which receive PHS research awards already have an effective compliance program. Nevertheless, the OIG states that this *Guidance* may serve as a useful comparison against which the institution can measure ongoing efforts. Furthermore, the *Guidance*'s eighth element of an effective compliance program – “defining roles and responsibilities and assigning oversight responsibility” – pertains specifically to research institutions. In regard to this element, the *Guidance* states that “institutions should clearly delineate the responsibilities of all persons involved with the conduct of federally supported research, including both administration or departmental personnel with oversight responsibility, as well as principal investigators and other personnel who are engaged in research.” The roles and responsibilities for each position should be clearly communicated and accessible.

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